CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40374

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

On this date, Dr. Paul Schwartz and Pat Beers Block contacted Thames Pharmacal to request the following information:

1) A commitment from the firm to test three batches of the drug substance, Triamcinolone Acetonide USP, for the residual solvents acetone, methanol , and dimethyformamide to validate the results provided by the active ingredient manufacturers. (Note: Thames desired to rely on the certificate of analysis supplied by the active ingredient suppliers in lieu of performing these tests on every batch of active ingredient received by Thames). Thames could submit the results of these tests in their next annual report.

2) Revise the active ingredient specification to include limits for these residual solvents.

We concluded our conversation with Mr. Rao stating he would provide this information as soon as possible.

DATE:
May 30, 2001

ANDA NUMBER:
40-374 (0.025%)
40-386 (0.5%)

PRODUCT NAME:
Triamcinolone Acetonide Ointment

FIRM NAME:
Thames Pharmacal Co., Inc.

FIRM REPRESENTATIVE:

Srinivasa Rao, Director
Regulatory Affairs

PHONE NUMBER:
631-737-1155

FDA REPRESENTATIVES:
Pat Beers Block

Paul Schwartz

SIGNATURES:

PS

ORIG: ANDAs 40-374; 40-386
CC : Division File
Chem I Telcon Binder

APPROVAL SUMMARY

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 40-374 Date of Submission: March 9, 2001 (Amendment)

Applicant's Name: Thames Pharmacal Co., Inc.

Established Name: Triamcinolone Acetonide Ointment USP, 0.025%

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):Do you have 12 Final Printed Labels and Labeling? Yes

Container Labels: (15 g, 30 g, 80 g, 453.6 g) – Satisfactory as of March 9, 2001 submission

Carton Labeling: (15 g, 30 g, 80 g) – Satisfactory as of March 9, 2001 submission

Professional Package Insert Labeling: Satisfactory as of March 9, 2001 submission

BASIS OF APPROVAL:
Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Kenalog Ointment

NDA Number: 11-600

NDA Drug Name: Triamcinolone Ointment 0.025%

NDA Firm: E. R. Squibb & Sons, Inc.

Date of Approval of NDA Insert: April 4, 1987

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: Side-by-side comparison

Basis of Approval for the Carton Labeling: Side-by-side comparison

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23	X		
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?		X	
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling(continued)	**Yes**	**No**	**N.A.**
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the			

insert labeling? Note: Chemist should confirm the data has been adequately supported.			
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?			X
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

NOTES/QUESTIONS TO THE CHEMIST:

Thames has a combined insert which includes its pending application for a 0.5% ointment preparation (ANDA 40-386). To approve this labeling, these applications must be approved together.

FOR THE RECORD:

1. Labeling review based on the approved labeling for the reference listed drug (Kenalog Ointment (E.R. Squibb & Sons, Inc.; revised April 1986; approved April 4, 1987). Incorporated recommendations made by Yana Mille, Puri Subramaniam, and Kent Johnson in FTR dated August 2, 1991 to the PRECAUTIONS and D&A Sections.

2. Packaging
   The innovator packages its 0.025% ointment in 15 g and 80 g tubes and 240 g jars.

   The applicant is proposing to package its 0.025% ointment in 15 g, 30 g and 80 g aluminum blind

ended tubes and 1 pound (453.6 g) PP Rexene jars.

3. Labeling
Agency revisions in the PRECAUTIONS and D&A Sections had been incorporated into the labeling. Please see the file folder for specifics regarding deletion of the Occlusive Dressing Technique and portions from the PRECAUTIONS (General) section.

It appears that the innovator's has separate insert labeling for each dosage form. However, Thames has combined labeling and has had it for many years. It should also be noted that Clay Parke's labeling is also combined for all the dosage forms.

Thames has several products currently approved:
86-275 – 0.5% cream
86-276 – 0.1% cream
86-277 – 0.025% cream
89-129 - 0.1% lotion
87-902 – 0.1% ointment

ANDA 40-386 is pending for a 0.5% ointment preparation. The firm has been notified that these applications must be approved together.

4. Inactive Ingredients – There are not discrepancies between the listing of inactives in the product labeling and in the C&C Statements.

5. USP Issues
USP – Preserve in well closed containers.
RLD – Store at RT
ANDA – Store at CRT 15-30°C (59-86°F). Protect from freezing.

6. Bioequivalence issues – Waiver granted 7/26/99

7. Patent/Exclusivities – None Pending

Date of Review:
March 26, 2001

Date of Submission:
March 9, 2001 (Amendment)

Primary Reviewer: /S/

Date: 3/26/01

Team Leader: /S/

Date: 3/27/2001

cc: ANDA: 40-374
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)

Review

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 40-374 Date of Submission: June 19, 2000 (Amendment)

Applicant's Name: Thames Pharmacal Co., Inc.

Established Name: Triamcinolone Acetonide Ointment USP, 0.025%

Labeling Deficiencies:

1. CONTAINER (15 g, 30 g, 80 g, 453.6 g) – Satisfactory in draft

2. CARTON (15 g, 30 g, 80 g) – Satisfactory in draft

3. INSERT – Satisfactory in draft

Please submit your labels and labeling in final print.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following web site for any approved changes –

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23	X		
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?		X	
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling(continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs		X	

Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)			
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.			
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?			X
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

NOTES/QUESTIONS TO THE CHEMIST:

Thames has a combined insert which includes its pending application for a 0.5% ointment preparation (ANDA 40-386). To approve this labeling, these applications must be approved together.

FOR THE RECORD:

1. **Labeling review based on the approved labeling for the reference listed drug (Kenalog Ointment (E.R. Squibb & Sons, Inc.; revised April 1986; approved April 4, 1987). Incorporated recommendations made by Yana Mille, Puri Subramaniam, and Kent Johnson in FTR dated August 2, 1991 to the PRECAUTIONS and D&A Sections.**

2. **Packaging**
   The innovator packages its 0.025% ointment in 15 g and 80 g tubes and 240 g jars.

   The applicant is proposing to package its 0.025% ointment in 15 g, 30 g and 80 g aluminum blind ended tubes and 1 pound (453.6 g) PP Rexene jars.

3. **Labeling**
   Agency revisions in the PRECAUTIONS and D&A Sections had been incorporated into the labeling. Please see the file folder for specifics regarding deletion of the Occlusive Dressing Technique and portions from the PRECAUTIONS (General) section.

   It appears that the innovator's has separate insert labeling for each dosage form. However, Thames has combined labeling and has had it for many years. It should also be noted that Clay Parke's labeling is also combined for all the dosage forms.

   Thames has several products currently approved:
   86-275 – 0.5% cream
   86-276 – 0.1% cream
   86-277 – 0.025% cream
   89-129 - 0.1% lotion
   87-902 – 0.1% ointment

   ANDA 40-386 is pending for a 0.5% ointment preparation. The firm has been notified that these applications must be approved together.

4. **Inactive Ingredients – There are not discrepancies between the listing of inactives in the product labeling and in the C&C Statements.**

5. **USP Issues**
   USP – Preserve in well closed containers.
   RLD – Store at RT
   ANDA – Store at CRT 15-30°C (59-86°F). Protect from freezing.
   (Thames has been asked to explain the need for the "Protect from freezing" statement.

6. **Bioequivalence issues – Pending**

7. **Patent/Exclusivities – None Pending**

Date of Review:
December 12, 2000

Date of Submission:
June 19, 2000 (Amendment)

~~Primary Reviewer:~~ /S/

Date: 12/12/00

~~Team Leader:~~ /S/

Date: 12/19/2000

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cc: ANDA: 40-374
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)

Review

REVIEW OF LABELING - LABELING REVIEW BRANCH

ANDA Number: 40-374 Date of Submission: June 1, 1999

Applicant's Name: Thames Pharmacal Co., Inc.

Established Name: Triamcinolone Acetonide Ointment USP, 0.025%

Labeling Deficiencies:

1. CONTAINER (15 g, 30 g, 80 g, 453.6 g)

   a. GENERAL COMMENT

      We note that you inadvertently submitted labeling of the reference listed drug for the 0.1% product strength with your side-by-side comparison. Please submit a comparison using approved labeling that is the same strength as that of your proposed product. Refer to 21 CFR 314.94(a)(8)(iv) for guidance.

   b. Prominently place the route of administration, "For External Use Only", on the principal display panel(s).

   c. We note that you have a pending application for the 0.5% ointment (ANDA 40-386) which is listed in the HOW SUPPLIED section of your labeling. Please be advised that these applications must be approved at the same time, or further revisions may be necessary.

2. CARTON (15 g, 30 g, 80 g) - See CONTAINER comments.

3. INSERT

   a. DESCRIPTION

      Change the molecular weight to "434.51" to be in accord with USP 23.

   b. PRECAUTIONS (Pregnancy Category C)

      Revise the subsection heading to: **Pregnancy**. Teratogenic Effects, Pregnancy Category C.

Please revise your labels and labeling, as instructed above, and submit in final print.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following web site for any approved changes –

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23	X		
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?		X	
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling(continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the		X	

NDA)			
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.			
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?			X
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

NOTES/QUESTIONS TO THE CHEMIST:

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   The applicant is proposing to package its 0.025% ointment in 15 g, 30 g and 80 g aluminum blind ended tubes and 1 pound (453.6 g) PP Rexene jars.

3. Labeling
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   89-129 - 0.1% lotion
   87-902 – 0.1% ointment

   ANDA 40-386 is pending for a 0.5% ointment preparation. The firm has been notified that these applications must be approved together.

4. Inactive Ingredients – There are not discrepancies between the listing of inactives in the product labeling and in the C&C Statements.

5. USP Issues
   USP – Preserve in well closed containers.
   RLD – Store at RT
   ANDA – Store at CRT 15-30°C (59-86°F). Protect from freezing.
   (Thames has been asked to explain the need for the "Protect from freezing" statement.

6. Bioequivalence issues – Pending

7. Patent/Exclusivities – None Pending

Date of Review:
October 31, 1999

Date of Submission:
June 1, 1999

Primary Reviewer: /S/

Date: 11/9/99

Team Leader: /S/

Date: 11/9/1999

cc: ANDA 40-374
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)
V:\FIRMSNZ\THAMES\LTRS&REV\40374na1.l
Review

Thames
PHARMACAL CO., INC.

OUTSIDE NEW YORK
(800) 225-1003

2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

CATEGORICAL EXCLUSIONS REQUEST

We hereby request the Food and Drug Administration under section 21 CFR 25-31 for a categorical exclusion.

We further certify that to the best of our knowledge Thames Pharmacal Co., Inc. is in compliance with all applicable local, state and federal regulations.

Thames Pharmacal Co., Inc.

By: _____ 3/09/01
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director, Regulatory Affairs